

## Actions Taken by FDA Center for Veterinary Medicine

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The following corrections or additions to the January 1999 list were made in July 1999

### New Approvals

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**NADA Number: 141-111**

Trade Name: Rimadyl® Chewable Tablets  
Ingredients: Carprofen  
Sponsor: Pfizer, Inc.  
Approval Date: May 14, 1999  
Status: Prescription only  
Route: Oral  
Species: Dogs  
Drug Form: Tablet  
Concentration: 25, 75, and 100 milligrams per tablet  
Indications: For the relief of pain and inflammation associated with osteoarthritis.  
Exclusivity: 3 years

21CFR 520.309

### Supplemental Approvals

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**NADA Number: 011-315**

**This supplemental application provides for use of neomycin sulfate in a new species (growing turkeys) in drinking water, establishes a tolerance in edible turkey tissues, and an acceptable daily intake.**

Trade Name: Neomix® 325/Neomix® AG 325 Soluble Powder  
Ingredients: Neomycin sulfate  
Sponsor: Pharmacia & Upjohn Company  
Approval Date: May 9, 1999  
Status: Over-the-counter  
Route: Oral  
Species: Growing turkeys, cattle, swine, sheep and goats  
Drug Form: Powder  
Concentration: 71.5 grams neomycin sulfate/3.5 ounce foil packet (equivalent to 50 grams neomycin)  
Indications: **Turkeys:** For the control of mortality associated with *Escherichia coli* organisms susceptible to neomycin sulfate.  
**Cattle (not for use in veal calves), swine, sheep, and goats:** For the treatment and control of bacterial enteritis caused by *Escherichia coli* organisms susceptible to neomycin sulfate.  
Tolerance: 556.430 Neomycin: The tolerances established for residues of parent neomycin in uncooked edible tissues of turkeys are as follows: 7.2 parts per million (ppm) in skin with adhering fat, 3.6 ppm in liver and 1.2 ppm in muscle. A tolerance of 7.2 ppm is established for residues of parent neomycin (marker residue) in uncooked edible kidney (target tissue), 7.2 ppm in fat, 3.6 ppm in liver, 1.2 ppm in muscle of cattle, swine, sheep, and goats. A tolerance of 0.15 ppm is established for neomycin in milk. The Acceptable Daily Intake (ADI) for total residues of neomycin is 6 micrograms/kilogram of body weight/day.  
Withdrawal: Turkeys - zero days  
Cattle (not for use in veal calves) - 1 day  
Sheep - 2 days  
Swine and goats - 3 days  
Exclusivity: 3 years

21CFR 520.1484 and 556.430

## **Actions Taken by FDA Center for Veterinary Medicine**

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### **Suitability Petition Action**

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Number: 99P-0923/CP1  
Sponsor: Pharmaderm, Veterinary Division of Altana, Inc.  
Petition: Request permission to file an ANADA for a generic new animal drug miconazole nitrate which differs from the pioneer product, Conofite<sup>®</sup> Cream 2%, Schering-Plough Animal Health Corporation, NADA 095-183, by the following characteristics: The generic will provide for a product containing 20 milligrams miconazole nitrate per gram of cream as opposed to the pioneer product which contains 23 milligrams miconazole nitrate per gram of cream.  
Action: Approved on June 28, 1999

### **Correction of a Final Rule**

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The Final rule published in the Federal Register of June 8, 1999 is to amend the Federal Register of March 2, 1999 which stated in the heading of § 520.534(d) "replacement calves". This notice removes the phrase "Replacement calves" and adds in its place "Calves".